CLAIMS

1. A method of enhancing an immune response to an antigen in a mammal, comprising administering to the mammal a safe and effective amount of 1) an IL-18 polypeptide or bioactive fragment or variant thereof, and 2) an immunogenic composition comprising an antigen or immunogenic derivative thereof and a CpG adjuvant.

2. A method according to claim 2 wherein the antigen or immunogenic derivative thereof is derived from an organism selected from the following group: Human Immunodeficiency virus HIV-1, human herpes simplex viruses, cytomegalovirus, Rotavirus, Epstein Barr virus, Varicella Zoster Virus, from a hepatitis virus such as hepatitis B virus, hepatitis A virus, hepatitis C virus and hepatitis E virus, from Respiratory Syncytial virus, parainfluenza virus, measles virus, mumps virus, human papilloma viruses, flaviviruses or Influenza virus, from *Neisseria spp, Moraxella spp, Bordetella spp; Mycobacterium spp.*, including *M. tuberculosis; Escherichia spp,* including *enterotoxic E. coli; Salmonella spp,; Listeria spp; Helicobacter spp; Staphylococcus spp.*, including *S. aureus, S. epidermidis;*; *Borrelia spp; Chlamydia spp.*, including *C. trachomatis*, *C. pneumoniae; Plasmodium spp.*, including *P. falciparum; Toxoplasma spp., Candida spp.*

3. A method of reducing the severity of a cancer in a patient, comprising administering to a patient in need thereof a safe and effective amount of 1) an IL-18 polypeptide or bioactive fragment or variant thereof and 2) an immunogenic composition comprising a tumour associated antigen or immunogenic derivative thereof and a CpG adjuvant.

4. A method according to claim 3, wherein the tumour associated antigen or immunogenic derivative thereof is selected from the group comprising: an antigen from the MAGE family, PRAME, BAGE, LAGE 1, LAGE 2, SAGE, HAGE, XAGE, PSA, PAP, PSCA, prostein, P501S, HASH2, Cripto, B726, NY-BR1.1, P510, MUC-1, Prostase, STEAP, tyrosinase, telomerase, survivin, CASB616, P53, or her 2 neu.

5. A method according to any of claims 1 to 4, wherein the IL-18 polypeptide or bioactive fragment or variant thereof and the immunogenic composition are administered simultaneously, separately or sequentially in any order.

6. A method according to claim 5 wherein the IL-18 polypeptide or bioactive fragment or variant thereof and the immunogenic composition are administered simultaneously in the form of a combined pharmaceutical preparation.

7. A method according to any of claims 1 to 6, wherein the IL-18 polypeptide or bioactive fragment or derivative thereof is from human or murine origin.

8. A method according to claim 7, wherein IL-18 is the polypeptide of SEQ ID NO.6 or SEQ ID NO.7 or bioactive fragment or derivative thereof.

9. A method according to any of claims 1 to 7, wherein the CpG adjuvant comprises a Purine, Purine, C, G, pyrimidine, pyrimidine sequence.

10. A method according to any of claims 1 to 8, wherein said CpG adjuvant is selected from the group comprising: TCC ATG ACG TTC CTG ACG TT (SEQ ID NO:1); TCT CCC AGC GTG CGC CAT (SEQ ID NO:2); ACC GAT GAC GTC GCC GGT GAC GGC ACC ACG (SEQ ID NO:3); TCG TCG TTT TGT CGT TTT GTC GTT (SEQ ID NO:4); TCC ATG ACG TTC CTG ATG CT (SEQ ID NO:5).

11. A method according to any of claims 1 to 8, wherein said CpG adjuvant contains at least two unmethylated CG repeats being separated at least by 3 nucleotides.

12. A method according to claim 11, wherein the immunostimulatory oligonucleotide contains at least two unmethylated CG repeats being separated by 6 nucleotides.

13. A combined preparation comprising as active ingredients the following individual components: (1) an IL-18 polypeptide or bioactive fragment or variant thereof and (2) immunogenic composition comprising an antigen and a CpG adjuvant, the active ingredients being for the simultaneous, separate or sequential use for the prophylaxis and/or treatment of infectious diseases, cancer, autoimmune diseases and related conditions.

14. A combined preparation according to claim 13 wherein components (1) and (2) are admixed in a composition.

15. A combined preparation according to claim 13 or 14 wherein the immunogenic composition comprises a tumour associated antigen or immunogenic derivative thereof and is prophylactically or therapeutically active against cancer.

16. A combined preparation according to claim 15 wherein the tumour associated antigen or immunogenic derivative thereof is selected from the group comprising: an antigen from the MAGE family, PRAME, BAGE, LAGE 1, LAGE 2, SAGE, HAGE, XAGE, PSA, PAP, PSCA, prostein, P501S, HASH2, Cripto, B726, NY-BR1.1, P510, MUC-1, Prostase, STEAP, tyrosinase, telomerase, survivin, CASB616, P53, or her 2 neu.

17. A combined preparation according to any of claims 13 to 16, wherein the IL-18 polypeptide or bioactive fragment or derivative thereof is from human or murine origin.

18. A combined preparation according to claim 17, wherein IL-18 is the polypeptide of SEQ ID NO.6 or SEQ ID NO.7 or an bioactive fragment or derivative thereof.

19. A combined preparation according to any of claims 13 to 18, wherein the CpG adjuvant is as defined in any of claims 9 to 12.

20. Combined preparation as claimed in any of claims 13 to 19 in which the immunogenic composition additionally comprises immunostimulant chemical selected from the group comprising: 3D-MPL, QS21, a mixture of QS21 and cholesterol, aluminium hydroxide, aluminium phosphate, tocopherol, and an oil in water emulsion or a combination of two or more of the said adjuvants.

21. Combined preparation as claimed in claim 20 wherein the immunogenic composition adjuvant comprises 3D-MPL, CpG, QS21, cholesterol, an oil in water emulsion.

22. Combined preparation as claimed in claim 21 wherein the oil in water emulsion comprises squalene, tocopherol and polyoxyethylenesorbitan monooleate (Tween 80).

23. Combined preparation as claimed in claim 20 wherein the immunogenic composition comprises QS21, cholesterol and a CpG adjuvant.

24. Combined preparation as claimed in any of claims 13 to 23, wherein both active components are in the form of injectable solutions.

25. A pharmaceutical kit comprising as active ingredients the following individual components: (1) an IL-18 polypeptide or bioactive fragment thereof and (2) an immunogenic composition comprising an antigen or immunogenic derivative thereof and a CpG adjuvant, the active ingredients being for the simultaneous, separate or sequential use for the prophylaxis and/or treatment of infectious diseases, cancer, and auto-immune diseases.

26. A pharmaceutical kit according to claim 25 wherein the immunogenic composition comprises a tumour associated antigen or immunogenic derivative thereof and is prophylactically or therapeutically active against cancer.

27. A pharmaceutical kit according to claim 26 wherein the tumour associated antigen or immunogenic derivative thereof is selected from the group comprising: an antigen from the MAGE family, PRAME, BAGE, LAGE 1, LAGE 2, SAGE, HAGE, XAGE, PSA, PAP, PSCA, prostein, P501S, HASH2, Cripto, B726, NY-BR1.1, P510, MUC-1, Prostase, STEAP, tyrosinase, telomerase, survivin, CASB616, P53, or her 2 neu.

28. A combined preparation as claimed in any of claims 13 to 23 for use in medecine.

29. A method as claimed in any of claims 1 to 12 which comprises the use of a combined preparation according to any of claims 13 to 24.

30. Use of an IL-18 polypeptide or bioactive fragment or derivative thereof in the manufacture of a medicament for the prophylaxis and/or treatment of patients

suffering from or susceptible to infectious diseases, cancer, autoimmune diseases and related conditions, and already primed with an immunogenic composition comprising an antigen or immunogenic derivative thereof and a CpG adjuvant.

31. Use of an immunogenic composition comprising an antigen or immunogenic derivative thereof and a CpG adjuvant in the manufacture of a medicament for the treatment of patients suffering from or susceptible to infectious diseases, cancer, autoimmune diseases and related conditions, and already primed with an IL-18 polypeptide or bioactive fragment or derivative thereof.

32. Use according to claim 30 or 31 wherein the antigen is a tumour associated antigen and the cancer is selected from the group comprising: breast cancer, lung cancer, NSCLC, colon cancer, melanoma, ovarian cancer, bladder cancer, head and neck squanmous carcinoma, oesophagus cancer.

33. Use according to any of claims 30 to 32, wherein the IL-18 polypeptide or bioactive fragment or derivative thereof is from human or murine origin.

34. Use according to claim 33, wherein IL-18 is the polypeptide of SEQ ID NO.6 or SEQ ID NO.7 or bioactive fragment or derivative thereof.

35. Use according to any of claims 30 to 34 wherein the CpG adjuvant is as defined in any of claims 9 to 12.